DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 3, 2015

Volcano Corporation
Elaine Alan
Senior Regulatory Affairs Specialist
1 Fortuna Drive
Billerica, MA 01821

Re: K150262
Trade/Device Name: Crux Vena Cava Filter System, Femoral; Crux Vena Cava Filter System, Jugular
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II
Product Code: DTK
Dated: February 3, 2015
Received: February 4, 2015

Dear Ms. Elaine Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150262

Device Name
Crux Vena Cava Filter System

Indications for Use *(Describe)*
The Crux Vena Cava Filter (VCF) System is indicated for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava (IVC) in the following situations:

- pulmonary thromboembolism when anticoagulants are contraindicated;
- failure of anticoagulant therapy in thromboembolic disease;
- emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
- chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Crux VCF may be removed according to the instructions contained in the section "Optional Retrieval of the Crux VCF" in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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DATE OF SUBMISSION: February 3, 2015

DEVICE: Vena Cava Filter

TRADE NAME: CRUX Vena Cava Filter System

COMMON NAME: Crux VCF System

PRODUCT CODE: DTK

CLASSIFICATION: 21 CFR 870.3375
Class II Device

PANEL: Cardiovascular

PREDICATE DEVICE: Crux Vena Cava Filter System, K122585

DEVICE DECRISPTION:
The Crux Vena Cava Filter (VCF) System is an endovascular medical device used in the prevention of recurrent pulmonary embolism (PE). The system is comprised of a self-expanding Nitinol filter delivered from a single-use, disposable 9Fr catheter, which can be used percutaneously to deploy the filter. The filter wireforms are composed of two opposing self-expanding Nitinol spiral elements connected at each end with Nitinol crimps. One of each wireform is formed into a sinusoidal shaped retrieval tail to aid in retrieval of the filter using a snare. Each retrieval tail has an atraumatic plasma ball and a radiopaque tantalum marker band to facilitate visualization. There are five tissue anchors attached to the wireform elements with Nitinol tubing. The filter is designed to treat IVC diameters of 17 to 28mm.

The delivery catheter for the Crux VCF System is a disposable, 9Fr introducer-sheath-compatible, single-use delivery catheter. The filter is provided loaded in the Crux VCF System for jugular or femoral approach delivery. The delivery catheter is an over-the-wire system, 0.035" guidewire-compatible, and is comprised of a polycarbonate inner shaft and a nylon outer shaft. The polyimide inner shaft is comprised of the guidewire lumen, and a flexible radiopaque tracking tip with a radiopaque marker band. The outer shaft has a radiopaque marker band, a Touhy-Borst hemostasis valve, and a one-way check-valve for flushing.

The filter can be retrieved with commercially available snares and sheaths via either the jugular or femoral approach.

INTENDED USE:
The Crux Vena Cava Filter System is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard endovascular techniques for placement of vascular access sheaths, angiographic catheters and guidewires should be employed.

The intended use of the Crux VCF System is unchanged by the content of this submission.

INDICATIONS FOR USE:
The Crux® Vena Cava Filter System is indicated for the prevention of recurrent pulmonary embolism via placement in the inferior vena cava (IVC) in the following situations:

- pulmonary thromboembolism when anticoagulants are contraindicated;
- failure of anticoagulant therapy in thromboembolic disease;
- emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced;
- chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Crux VCF may be removed according to the instructions contained in the section "Optional Retrieval of the Crux VCF" in patients who no longer require a vena cava filter. Retrieval of the filter can be performed by femoral or jugular approach.

COMPARISON OF CHARACTERISTICS:
This submission is for labeling changes only. The devices are identical in terms of design, materials, specifications, principles of operation, and fundamental scientific technology.

PERFORMANCE DATA:
Bench and animal device testing was conducted to confirm the performance of the device. There are no known recognized standards relevant to the proposed labeling changes. Bench testing relative to infusion of contrast media was conducted in accordance with FDA Guidance for Industry and FDA Staff "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty PPTCA) Catheters". Tests performed to assess the impact of the proposed labeling changes were:

Bench testing:

- Flow Analysis using Computational Flow Dynamics (CFD) Modelling to examine blood flow past the Crux VCF with the inflow from the right and left renal veins
- VCF Radial Force Test to evaluate the effect of the proposed pararenal placement on radial forces
- Catheter Pressure Integrity testing to show that the catheter delivery catheter is designed to perform power injection of contrast media

Animal testing:

- Work flow Evaluation of Placement to evaluate the clinical workflow of deploying the Crux VCF when placed in a pararenal location
- Power Injection Testing to evaluate the use of a power injector to inject contrast media through the Crux VCF delivery catheter during simulated clinical use

All tests met the pre-determined acceptance criteria.

Biocompatibility testing was not conducted on the device as there were no changes made to materials or sterilization.

CONCLUSION:
Completion of these tests concluded that the proposed Crux VCF System is substantially equivalent to the predicate device.